K001624

JAN 2 5 2001

GEBAUER COMPANY

Pharmaceutical Preparations

510(k) SUMMARY

Establishment Name:	Gebauer Company (Manufacturer)
Address:	9410 St. Catherine Ave. Cleveland, OH 44104
Phone Number:	(216) 271-5252
Fax Number:	(216) 271-0910
Contact Person:	Denise E. Spellman (Official Correspondent)
Date Summary Prepared:	4/28/00
Device Name:	Gebauer's Fluori-Methane
Classification Name:	Vapocollant
Predicate Products:	Gebauer's Ethyl Chloride, Fine & Medium Sprays Fluori-Methane, Fine Nozzle Fluori-Methane SS

Device Description:

Gebauer's Fluori-Methane is a prescription device consisting of a mixture of two organic chemicals and a precise delivery system. The chemical is self-aerosolized to deliver a pinpoint stream spray.

Intended Use of Device:

Gebauer's Fluori-Methane is a topical anesthetic intended to treat restricted motion associated with myofascial pain caused by trigger points. It will also control pain associated with injections and provide temporary relief from the pain of minor sports injuries.

9410 ST. CATHERINE AVE. • CLEVELAND, OHIO 44104 • PHONE 216-271-5252 • FAX 216-271-5335 • TOLL FREE 1-800-321-9348

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

Both the new device and the predicate devices aerosolize single or a mixture of two organic chemicals. The cooling action experienced by the patient is caused by the evaporation of the chemical or chemical mixture from the patient's skin. Two of the predicate devices utilize delivery mechanisms identical to that utilized by the new device. One of the predicate devices dispenses a chemical mixture identical to that dispensed by the new device.

Both the new device and the predicate devices cool the skin and a sufficient amount of the underlying tissue to provide pre-injection anesthesia. Four studies conducted between 1955 and 1997 show a cooling effect comparable to that shown by Gebauer's Ethyl Chloride and consequently show equally effective relief from the pain of injections.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 5 2001

Suzanne Wojcik
Director, Regulatory Affairs
Gebauer Company
9410 St. Catherine Avenue
Cleveland, OH 44104

Re: K001624
Trade Name: Fluori-Methane
Regulatory Class: unclassified
Product Code: MLY
Dated: November 28, 2000
Received: November 30, 2000

Dear Ms. Wojcik:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K001624

Device Name: Gebauer's Fluori Methane

Indications For Use:

Gebauer's Fluori Methane: Gebauer's Fluori Methane is a topical anesthetic intended to treat restricted motion associated with myofascial pain caused by trigger points. It will also control pain associated with injections and provide temporary relief from the pain of minor sports injuries.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Optional Format 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001624